UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JILL A. WHITCOMB,

Plaintiff,

v. Case No. 17-CV-14

THOMAS E. PRICE, M.D.
Secretary of the U.S. Department of Health
and Human Services,

Defendant.

PLAINTIFF'S REPLY IN RESPONSE TO DEFENDANT'S REPONSE TO PLAINTIFF'S REQUEST FOR JUDICIAL REVIEW

I. MS. WHITCOMB'S COMPLAINT AND SHOWING

In May 2015, this Court remanded this case to the Secretary (through the Appeals Council) with instructions to determine "whether a continuous glucose monitor is reasonable and necessary for Whitcomb and not otherwise excluded." Record at 220. In turn, the Council remanded this case to the ALJ Bush.

A. The CGM is Reasonable and Medically Necessary for Ms. Whitcomb

As detailed in Ms. Whitcomb's opening papers, Judge Bush determined that a CGM is "medically reasonable and necessary for [Ms. Whitcomb]." Record at 32-34. This was so because the CGM alerted Ms. Whitcomb to the glucose highs and lows that she would not otherwise be able to detect and, literally, kept Ms. Whitcomb non-comatose, out of the hospital and alive ("the CGM has been a life-saver for [Ms. Whitcomb]"). Record at 32. Judge Bush's finding that a CGM is necessary to prevent life-threatening complications has not been challenged or addressed by the Secretary either before the Council or before this Court.

Accordingly, it is established that a CGM is medically reasonable and necessary for Ms. Whitcomb.

B. CGM is Not Otherwise Excluded from Coverage

With respect to the Court's instruction to determine whether a CGM is "otherwise excluded" from coverage, Judge Bush determined that a CGM qualifies as durable medical equipment (DME), pursuant to Section 1861(n) of the Social Security Act, the regulatory definition of DME found at 42 C.F.R. §414.202, is within the terms of National Coverage Determination (NCD) 280.1, also falls within NCD 40.2 and Local Coverage Determination L27231, and is not otherwise excluded from coverage. Record at 31, 33, 34.[1] Subsequently, the Secretary through the Council asserted that a CGM is not DME because it does not "serve a medical purpose"/"serve a primary medical purpose". Record at 10. Instead, using a non-statutory term, the Secretary asserted that a CGM is "precautionary" stating: "Where an enrollee must still use another device to accomplish the medical purpose at issue, the device is essentially used as an additional precaution, but not for a primary medical purpose." Record at 10.

In her opening papers before this Court, Ms. Whitcomb showed that the Secretary's Decision was arbitrary and capricious, and not supported by substantial evidence. In particular, Ms. Whitcomb showed that the medical community as a whole (including the FDA) consider a CGM to be primarily a medical device, there is no use for a CGM other than a medical purpose, that a CGM is the only device that can test with the frequency required and while the user is sleeping, alert a user of an otherwise undetectable low, and that a CGM is the only device that can provide trend information. Motion at 4-5. Ms. Whitcomb also showed that the Secretary

[1] With respect to NCD 40.2 and LCD L27231, as this Court has already found, those documents are silent as to whether CGMs are included or excluded from them. The ALJ found that NCD 280.1, which contains a DME list indicated a glucose monitor was covered if a patient (as opposed to a device) satisfies the criteria of NCD 40.2. Record at 33.

failed to consider any of these facts, including the standard of care, opinions of experts, peer-reviewed literature, practice guidelines, consensus statements and the independent determinations of the payer community.[2] Motion at 12, 13. Record at 18, Attachment 7. Further, Ms. Whitcomb showed that the decision in her case was inconsistent with numerous other coverage decisions with respect to CGMs. Motion at 12. Finally, Ms. Whitcomb showed that the Secretary's effort to rely on the non-statutory and undefined term "precautionary" was non-sensical, when numerous devices are covered as DME although their purpose is adjunctive or backup to other devices/or tests. Motion at 18-20.

II. THE SECRETARY'S RESPONSE TO MS. WHITCOMB'S SHOWING

As an initial matter, on its face, the idea that a CGM is not "primarily a medical device" or is "non-medical" is difficult to follow. A CGM cannot make waffles, wash a car, or do WestLaw searches. In Ms. Whitcomb's opening papers, she showed that a host of authorities (including the FDA) consider a CGM to be primarily a medical device and that the Secretary failed to consider any of these in making a contrary determination. Motion at 3 - 5, 12, 13. Record at 18, Attachments 1-4, 7. Both below and in his Response, the Secretary is silent as to these authorities. Accordingly, Ms. Whitcomb's showing of arbitrary and capricious and/or not supported by substantial evidence in this regard is unrebutted.

Moreover, as a general matter, Judge Bush noted that his decision as to DME was controlled by NCD 280.1. Record at 33. The NCD provides, in part, that an item is DME if it "is primarily and customarily used to serve a medical purpose." NCD 280.1. Applying this standard, Judge Bush found that a CGM is DME because it meets each part of the five part test

[2] Contrary to the Secretary's assertion, Ms. Whitcomb's assertion that the more than 95% of commercial payers cover CGM is not based simply based on her physician's statement. See e.g. Record 18 at Attachment 4, wherein the American Medical Association acknowledges more than 95% of commercial payers cover CGM.

specified. Record at 31. The Secretary's contrary Decision seeks to recast the NCD as defining DME as only those things "used to serve a *primary* medical purpose." Record at 10 (emphasis added). That is a dramatic change from what is provided by the statute, regulations and NCD. Although the statute and the NCD focus on whether the device is typically used for a medical purpose or for some other purpose, the Secretary's effort to recast the NCD focuses on the relative importance of the medical use.[3] In his Response to Ms. Whitcomb's opening papers, the Secretary continues to advance this new test, which is directly contrary to the statute, regulations and NCD. Thus, on this ground alone, the Secretary's Decision should be reversed.

Using his newly created test that only equipment that serves a "primary medical purpose" are DME, the Secretary relied on the non-statutory term "precautionary" to deny coverage. In her opening papers, Ms. Whitcomb showed that the Secretary's new test was arbitrary and capricious. In particular, the Secretary's claim that "[w]here an enrollee must still use another device to accomplish the medical purpose at issue, the device is essentially used as an additional precaution, but not for a primary medical purpose"[4] could not be squared with numerous other devices already determined to be DME. For example, the Secretary covers Pacemaker *monitors* as DME and those would not fit the Secretary's newly created, non-statutory condition. Motion at 19. The Secretary's coverage of such adjunctive devices and presumptive laboratory tests necessary demonstrates that the Secretary recognizes such devices serve a primary medical purpose.[5] Further, because the Secretary acknowledges that a finger stick test simply confirms

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[3] The relative importance of the medical use of the device is already captured in the "medically reasonable and necessary" requirement and simply has nothing to do with whether a device is DME. Here, that a CGM is medically reasonable and necessary for Ms. Whitcomb is unchallenged.

[4] See Record at 10.

[5] Medicare covers a hospital bed as DME when "the patient's condition requires positioning of the body; e.g., to alleviate pain, to prevent contractures, avoid respiratory infections, in ways not feasible in an ordinary bed." NCDs 280.1 and 280.7. A hospital bed does not treat the underlying condition and does

the CGM result (and not the obverse), the Secretary necessarily concedes that a CGM is the primary means by which such a diabetic controls their diabetes. Response at 8. Accordingly, even taken on its own terms, the Secretary's Decision, relying on the new test, is arbitrary and capricious. The Secretary's responsive papers before this Court are silent in this regard and Ms. Whitcomb's showing is unrebutted.

Further, even under this new "primary medical purpose" standard, the CGM would satisfy Medicare coverage criteria. As noted above, no other medical device provides the glucose trend information or is capable of detecting the rapid and large glucose swings Ms. Whitcomb experiences. The Secretary does not suggest Ms. Whitcomb would be able to manage her condition without a CGM. Ms. Whitcomb uses the trend information in the short term to manage her diabetes and her clinician uses the trend information to devise a long-term management plan (e.g, the patient should generally have more insulin during the summer months, while sleeping, while exercising, when performing a stressful job). Thus, even considering the Secretary's new test, the Secretary's conclusion that CGM's are merely "precautionary" must be rejected.

Along these same lines, HHS' Civil Remedies Division has also held that the assertion that a CGM is "precautionary" is invalid under the reasonableness standard.[6] See Record at 18, Attachment 7. In his Decision, the Secretary's only response to that finding was to dispute whether the finding is binding on the Secretary. Record at 11. That response does not address

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not direct a therapy – it is used to prevent the exacerbation of the condition and consequences therefrom. The fact that other devices might be used to treat a patient's condition does not deprive a hospital bed of a medical purpose.

[6] In his Response, the Secretary cited the Civil Remedies Division Decision in support of the proposition that a determination of whether an item is precautionary relates to whether it is primarily and customarily used for a medical purpose (see Response at 19), but fails to note that the Civil Remedies Division Decision concluded there was no substantial evidence that a CGM did not meet the definition of DME.

the lack of explanation/failure to address the underlying determination, i.e., that a CGM is not precautionary.[7] Accordingly, again, the Secretary has failed to respond to Ms. Whitcomb's showing that the Secretary's Decision is not the result of difference in point of view or the product of agency expertise because the Secretary has failed to explain the contrary conclusion (except by simply re-casting the statute and the NCD). See *Motor Vehicle Manufacturers Ass'n of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 63 (1983).

That CGMs must be calibrated and/or should have readings confirmed with finger sticks has no bearing on whether a device is "primarily used for a medical purpose" and is therefore DME. Nothing in the statutory or regulatory definition of DME requires a DME to function without calibration or confirmation. See NCD 280.1 and 42 C.F.R. § 414.202.

Finally, Ms. Whitcomb's opening papers noted that more than 40 final ALJ decisions have concluded that CGMs were DME. Motion at 22. Accordingly, the Secretary's decision denying coverage in this case was arbitrary and capricious. In response to Ms. Whitcomb's showing, the Secretary contends that ALJ decisions are non-precedential and, in any event, that those cases are "unspecified." Response at 21. As noted in Ms. Whitcomb's opening paper, the very essence of "arbitrary and capricious" is when functionally indistinguishable cases have different results. See Motion at 22 (citing *Independent Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1246, 1260 (D.C. Cir. 1996). Thus, when 40 other cases conclude that CGMs are DME and are covered by Medicare, absent compelling reasoning, a decision that CGMs are not DME is arbitrary

[7] Although the HHS Civil Remedies Division Ruling was vacated on procedural grounds that the Article could not be challenged through the LCD process as this Court previously recognized, the analysis in the Ruling, which considered the peer-reviewed literature and consensus of experts, underscores that no evidence supported the proposition that a CGM is precautionary. The written evidence was so overwhelming that the judge determined a hearing to take the testimony of experts was unnecessary and ruled favorably on the record.

and capricious. To the extent the Secretary's Decision is not vacated based on its arbitrary and capricious determination that an adjunctive medical device is not primarily a medical device, or its new test (not supported by substantial evidence) that a CGM does not serve a primary medical purpose, the Secretary's Decision should be vacated because it is arbitrary and capricious relative to other final decisions finding that a CGM is DME and covered by Medicare.

On review, Ms. Whitcomb concedes that the citation in her opening brief did not specifically identify each of the 40 decisions. Motion at 12. Nevertheless, the Secretary does not deny the numerous administrative law judge decisions finding CGM is DME and covered by Medicare, or that those decisions constitute final agency determinations. See 42 C.F.R. §405.1048. It would be surprising if the Secretary is unaware of so many final decisions that issued before and after Ms. Whitcomb's request for CGM coverage. Further, it is irrelevant whether those ALJ decisions involved Medicare Advantage Plans or Original Medicare. If a CGM did not serve a medical purpose and did not fit within a Medicare benefit category, no Medicare beneficiary, whether covered by Original Medicare or a Medicare Advantage Plan, would have been able to secure coverage through the Medicare appeals process.[8] The Secretary proffers no explanation of why he determined a CGM served a medical purpose and was covered under the Medicare DME benefit for so many other diabetic Medicare beneficiaries, but reached a contrary conclusion with respect to Ms. Whitcomb's request. Nonetheless, in an effort to address the Secretary's claim that he does not know of the 40 final decisions of his agency, the link cited in Ms. Whitcomb's opening papers has been updated to specifically list each of those final decisions. See http://dparrishlaw.com/medicare-acknowledges-dexcoms-g5-as-a-covered-medicare-benefit/

[8] Any time an administrative law judge renders a decision that is contrary to law, the relevant Medicare contractor can seek reversal by the Medicare Appeal Council, the Medicare Advantage Plan can appeal the decision (a CGM would have been denied by a Medicare Advantage Plan or it would not have entered the Medicare appeals process), or the Council can conduct "Own Motion Review" to ensure that ALJ's are render decisions consistent with Medicare law. See 42 C.F.R. §§405.1000, 405.1102, 405.1110.

Overall, the Secretary did not respond to Ms. Whitcomb's showing that the Decision was arbitrary and capricious/not supported by substantial evidence and/or simply contrary to law and fact. Instead, the Secretary seeks to avoid the requirements of both the statute, regulations and the NCD 280.1 by simply changing the operative language. That approach is not justified.

III. THE SECRETARY'S OTHER ARGUMENTS AND EFFORTS

Although the Secretary fails to address the arguments and evidence raised by Ms. Whitcomb, or demonstrate that the Decision was supported by substantial evidence and not otherwise arbitrary and capricious, the Secretary attempts to introduce new evidence, revisit this Court's prior ruling, argue for deference on other new sources which are not promulgated with notice and comment, and confuses the Record.

A. Ruling No. 1682 Is Irrelevant

Because nothing in the Record supports the Secretary's determination that a CGM does not serve a medical purpose, the Secretary urges the Court to consider a ruling that CMS issued in January 2017, long after Ms. Whitcomb sought coverage and which the Secretary did not and could not have relied on in issuing the Decision. Response at 9 - 10. Not only did Ruling 1682 issue after this litigation arose, the Ruling 1682 explicitly states it should not be given effect to any claims or requests before January 12, 2017. Thus, on its face, the January ruling is irrelevant. In either event, Ruling 1682 acknowledges that before January 2017 CMS misunderstood the durable component of a CGM and that CGMs provide trend information not provided by finger sticks and detect glucose highs and lows that cannot be detected finger sticks. The Secretary's effort to support an unsupported Decision by citation to a ruling the post-dates and clearly was not the basis of the Secretary's Decision, is not in the Record, explicitly states

should not apply, and suffers from facial deficiencies which have not been tested and which are beyond the scope of this case, [9] should be rejected.

B. Neither the Article Nor A Manual Provision are Entitled to Deference

Although this Court already determined the Article cited in the Secretary's prior decision on this matter is not entitled to deference, the Secretary attempts to revive the point stating the Article may address a benefit category determination. Response at 8. The Secretary cites Medicare Program Integrity Manual Chapter 13.1.3 for such a proposition. However, the cited manual section simply describes a policy conversion process that occurred in 2003 with respect to local medical review policies, before LCDs existed, and the effort to ensure that LCDs alone contained determinations of medical necessity. Such a conversion effort does not reflect the LCDs and Articles that have issued since 2003, including the Article and LCD relevant in this case.

Having lost the argument that an Article is entitled to deference, the Secretary now asks the Court to give substantial deference to a manual section that states equipment that is precautionary does not fall within the DME benefit. Response at 20. As an initial matter, the cited manual section provides an exemplar of precautionary equipment – a pre-set back up oxygen tank - an exemplar that underscores the difference of a CGM which is Ms. Whitcomb's continuous and primary means of managing her diabetes. Thus, even if this Court gave

[9] For example, although consistent with its FDA approval, a CGM requires five sensors a month for effective use of the CGM, in Ruling 1682, CMS has announced it will only reimburse four sensors a month and will not reimburse additional finger sticks to cover the shortage. Because Medicare suppliers must provide all supplies necessary for DME (which would require five sensors and sufficient finger sticks for calibration, suppliers have declined to provide CGMs to Medicare beneficiaries in view of the unreimbursed cost. Further, Ruling 1682 asserts if a Medicare beneficiary uses a cell phone application to share their blood glucose values with a physician or caretaker, Medicare will not cover the CGM – a novel restriction that is contrary to Medicare's telehealth initiative and which raises a host of issues regarding Medicare's attempt to prevent Medicare beneficiaries from using a cell phone to track a medical condition and Medicare's possible infringement on First Amendment rights.

substantial deference to the manual provision, it does not support the Secretary's position, it undercuts it. Further, just like local policy articles, manuals are not promulgated through notice and comment. Finally, the Secretary cites no legal support for the proposition that a manual provision, or his interpretation of a manual provision, is entitled to substantial deference.[10]

C. The Secretary Confuses the Record

The Secretary misquotes United's policy when he states "Long term use or frequent use of continuous glucose monitoring will be denied as not medically necessary." Response at 16. The quotation is taken from the section 5a of United's internal policy which explicitly refers to professional CGM (Record at 907 - 908), e.g., a CGM used by a professional health care provider such as a doctor.[11] The next section of the policy, relating to a personal CGM, recounts that no NCD or LCD specific to CGM exists and notes the "precautionary" language in the discredited article. More importantly, the Secretary's Response ignores United's national policy with respect to Continuous Glucose Monitoring (Record at 18, Attachment 6 at 3) which states:

> Long-term continuous glucose monitoring for personal use at home is proven and **medically necessary** as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes who meet EITHER of the following criteria AND have demonstrated adherence to a physician ordered diabetic treatment plan:
>
> Have been unable to achieve optimum glycemic control as defined by the most current version of the American Diabetes Association (ADA) Standards of Medical Care in Diabetes; or
> Have experienced hypoglycemia unawareness and/or frequent episodes of hypoglycemia.

Thus, United's national policy explicitly recognizes that a CGM is medically necessary for individuals such as Ms. Whitcomb.

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[10] To the extent the Secretary implies that the discredited Article reflects the Secretary's interpretation of the cited manual provision and is binding on a Medicare Advantage Plan (see Response at 8), United's Medicare Advantage policy clearly demonstrates such interpretations are non-binding. The Secretary concedes United explicitly covers CGM on a short term basis for Medicare beneficiaries. See Response 15-16 and Record at 907-908. Thus, Medicare Advantage Plans are not restricted from covering CGM.

[11] The cited section explicitly states, "This policy addresses provisional CGM." Record at 907.

Similarly, the Secretary misquotes the Medicare Program Benefit Manual when he asserts that "payment will be barred "for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case." Response at 6-7. The quoted language comes from a manual provision noting that although an item might be DME and generally covered by Medicare, if a particular patient cannot benefit from the DME, it will not be covered if it cannot serve a therapeutic purpose for that beneficiary. See Medicare Program Integrity Manual, Ch. 15, §110.1-C.

IV. CONCLUSION

The Secretary's Decision is contrary to law and facts. The overwhelming evidence is a CGM is the only medical device that allows Ms. Whitcomb to manage her illness. A CGM is primarily and customarily used for a medical purpose and meets the definition of DME. A CGM performs medical functions not performed by any other medical device and is the only device that enables beneficiaries with diabetes and unawareness to control their disease. The Decision is not supported by substantial evidence in the Record, or any relevant evidence. Further, the Decision is arbitrary and capricious as it conflicts with NCD 280.1, numerous NCD's extending coverage to adjunctive medical devices and coverage of tests that are confirmed, and his prior and subsequent determinations regarding CGM. For the foregoing reasons, this Court should grant Plaintiff Whitcomb's Motion.

Date: August 11, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, on the 11th day of August, 2017, Robert Theine Pleld of McNally Peterson, S.C. electronically filed Plaintiff's Reply in Response to Defendant's Response to Plaintiff's Request for Judicial Review, with supporting papers, using the Eastern District of Wisconsin CM/ECF system which will automatically send email notification of such filing to counsel of record for Defendant.

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